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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,711	01/24/2000	David S. Roberts	PC10299A	6167
23913	7590	04/16/2004	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/489,711

**Applicant(s)**

ROBERTS ET AL.

**Examiner**

S. Devi, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-17, 24-28, 30 and 31 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-17, 24-28, 30 and 31 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**Request for Continued Examination**

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 01/26/04 has been entered.

**Applicants' Amendment**

2) Acknowledgment is made of Applicants' amendment filed 09/29/03 in response to the final Office Action mailed 03/25/03.

**Status of Claims**

3) Claims 14, 18-23 and 29 have been canceled via the amendment filed 09/29/03.  
Claims 13, 16, 17, 28 and 30 have been amended via the amendment filed 09/29/03.  
New claim 31 has been added via the amendment filed 09/29/03.  
Claims 13-17, 24-28, 30 and 31 are pending and are under examination.

**Prior Citation of Title 35 Sections**

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

**Prior Citation of References**

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

**Rejection(s) Moot**

- 6) The rejection of claim 14 made in paragraph 14 of the Office Action mailed 03/25/03 under 35 U.S.C. § 102(b) as being anticipated by Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996) as evidenced by Barenholz *et al.* (US 6,156,337 - already of record), is moot in light of Applicants' cancellation of the claim.
- 7) The rejection of claim 14 made in paragraph 15 of the Office Action mailed 03/25/03 under 35 U.S.C. § 102(b) as being anticipated by Groschup *et al.* (*Epidemiol. Infect.* 107: 637-49, 1991 - Applicants' IDS) as evidenced by Barenholz *et al.* (US 6,156,337 - already of record), is moot in light of Applicants' cancellation of the claim.
- 8) The rejection of claim 29 made in paragraph 13 of the Office Action mailed 03/25/03 under 35 U.S.C. § 112, first paragraph, as being non-enabling with regard to the scope, is moot in light of Applicants' cancellation of the claim.

**Rejection(s) Withdrawn**

- 9) The rejection of claims 28 and 30 made in paragraph 12(a) of the Office Action mailed 03/25/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.
- 10) The rejection of claim 16 made in paragraph 12(b) of the Office Action mailed 03/25/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 11) The rejection of claims 13 and 16 made in paragraph 11 of the Office Action mailed 08/28/02 and maintained in paragraph 11 of the Office Action mailed 03/25/03 under 35 U.S.C § 102(b) as being anticipated by Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995) as evidenced by Petre *et al.* (US 6,013,264, filed 21 May 1993), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).
- 12) The rejection of claim 17 made in paragraph 13 of the Office Action mailed 03/25/03 under 35 U.S.C § 112, first paragraph, as being non-enabling with regard to the scope, is withdrawn in light of Applicants' amendment to the claim and/or the base claim.
- 13) The rejection of claims 13, 15 and 24 made in paragraph 14 of the Office Action mailed 03/25/03 under 35 U.S.C § 102(b) as being anticipated by Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996) as evidenced by Barenholz *et al.* (US 6,156,337), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).
- 14) The rejection of claims 13 and 24 made in paragraph 15 of the Office Action mailed 03/25/03 under 35 U.S.C § 102(b) as being anticipated by Groschup *et al.* (*Epidemiol. Infect.* 107: 637-49, 1991) as evidenced by Barenholz *et al.* (US 6,156,337), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).
- 15) The rejection of claims 13, 16, 17 and 25-27 made in paragraph 16 of the Office Action mailed 03/25/03 under 35 U.S.C § 103(a) as being unpatentable over Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-9, 1996), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).
- 16) The rejection of claims 13, 16-18 and 28 made in paragraph 17 of the Office Action mailed 03/25/03 under 35 U.S.C § 103(a) as being unpatentable over Dayalu *et al.* (WO 91/18627) in view of Sato *et al.* (*Vet. Microbiol.* 43(2): 173-182, 1995), and Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996) and Barenholz *et al.* (US 6,156,337, 09 September 1996), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).
- 17) The rejection of claims 17, 28 and 30 made in paragraph 18 of the Office Action mailed 03/25/03 under 35 U.S.C § 103(a) as being unpatentable over Dayalu *et al.* (WO 91/18627) in view of Groschup *et al.*

(*Epidemiol. Infect.* 107: 637-49, 1991), or Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996) and Barenholz *et al.* (US 6,156,337, 09 September 1996), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

**Rejection(s) under 35 U.S.C § 102**

**18)** Claims 13, 15-17, 24-28, 30 and 31 are rejected under 35 U.S.C § 102(b) as being anticipated by Frantz *et al.* (US 5,695,769) as evidenced by Barenholz *et al.* (US 6,156,337 - already of record).

The term 'about' with regard to the percent v/v of the stabilizing agent, or the adjuvant ingredients recited in the instant claims, is interpreted in this rejection as encompassing  $\pm 10$ .

Frantz *et al.* disclosed a vaccine composition comprising a culture fluid fraction from a formalin-inactivated *Erysipelothrix rhusiopathiae*. The fraction is clarified by centrifugation and therefore is substantially free of cells of *Erysipelothrix rhusiopathiae*. The fluid antigen fraction is then concentrated by ultrafiltration to a calculated OD of 16.67. See sections 'B. Inactivation of Bacteria' and 'C. Vaccine Fluid Preparation' at the upper half of column 17. The antigen composition further comprises an aluminum hydroxide gel, i.e., REHYDRAGEL or REHYDRAGEL HPA, or calcium phosphate, or alum at a concentration of between 15 and 60% (see lines 55-65 in column 6; paragraph bridging columns 6 and 7; and the first full paragraph in column 7). The antigen composition comprises Drakeol, i.e., lecithin and mineral oil emulsion at various concentrations, and between 0.7% to 3.2% Tween 80 and 0.3% to 1.8% Span. The lecithin and mineral oil emulsion is present at a concentration of 5 to 40%, or 10% (see claims and second full paragraph in column 1), or 8% v/v of amphiphilic surfactant (see the Table in column 19). That aluminum hydroxide in Frantz's composition intrinsically served as a stabilizing agent is inherent from the teachings of Frantz *et al.* in light of what was known in the art. For instance, Barenholz *et al.* taught the dual role of aluminum hydroxide both as an adjuvant and as a stabilizer in microbial vaccines (see column 13, last two lines).

The disclosure of Frantz *et al.* anticipates the instant claims. Barenholz *et al.* is **not** used as a secondary reference in combination with Frantz *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Frantz *et al.* See *In re Samour* 197 USPQ 1 (CCPA 1978). The prior art antigenic composition is viewed as the same as the instant composition. Although Frantz *et al.* are silent about the stability of the composition at 2°C to 8°C for at least one year and induction of immunity to weaned pigs for six months, the prior art antigen composition is viewed as the same as Applicants' antigen composition, and therefore is expected to have the stability at 2°C to 8°C for at least one year and induction of immunity to weaned pigs for six months. The property of stability at 2°C to 8°C for at least one year and induction of immunity to weaned pigs for six months are viewed as uncharacterized inherent functions

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inseparable from the prior art composition, absent evidence to the contrary.

Claims 13, 15-17, 24-28, 30 and 31 are anticipated by Frantz *et al.*

**Remarks**

- 19) Claims 13, 15-17, 24-28, 30 and 31 stand rejected.
- 20) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives papers 24 hours a day and seven days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.
- 21) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.
- If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

April, 2004

  
S. DEVI, PH.D.  
PRIMARY EXAMINER